

## Inventory of CLIA-Waived Tests Performed in Washington State

by Kathy LaBeau

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), laboratory tests are categorized according to their complexity. The simplest laboratory examinations or procedures are categorized as "waived" and have minimal associated regulatory oversight and standards for compliance.

CLIA-waived testing, however, represents a large segment of all clinical laboratory testing performed. More than 800 waived test systems are currently available for 40 different analytes. In Washington State, 91% of all 2,770 licensed sites perform one or more waived tests, with 41% performing waived tests exclusively.

At the federal level, there is much concern and debate over the criteria to categorize tests as waived and the degree of oversight necessary to assess that laboratories are using waived test systems correctly. Information about utilization of specific waived tests and devices has been unavailable in the CLIA database, despite the widespread use and impact on patient care.

As part of a cooperative agreement research project with the Centers for Disease Control and Prevention (CDC), I have created a computer database of all waived tests (a total of 11,005) used by all licensed testing sites in Washington State. Confidentiality has been maintained to

prevent the identification of individual laboratories. The data are available in aggregate formats, linked to demographic categories of interest. The general patterns of waived test usage for Washington State medical test sites are likely reflective of those nationwide, and may be used as a reference for federal government agencies as well as a variety of other interest groups for a variety of purposes.

In Washington State, the Office of Laboratory Quality Assurance will use this inventory of waived tests to target their efforts in providing technical assistance, preparing handouts, developing educational resources on their website, and conducting training courses pertaining to waived testing issues.

In this article, I briefly share some of the findings from this inventory.

### Who oversees testing in waived sites?

Under CLIA and the Washington Medical Test Site (MTS) regulations, there are no qualifications specified

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### Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:  
[www.doh.wa.gov/hsqa/fsl/LQA\\_Home.htm](http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm)

Anemia	Point-of-Care Testing
ANA	PSA
Bleeding Disorders	Renal Disease
Chlamydia	STD
Diabetes	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Lipid Screening	Wellness

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for directors of sites that perform only waived testing. The following table summarizes the backgrounds of directors of the 1134 waived testing sites in Washington State.

Background of waived test site director	Number	Percent
Physician (MD, DO, DPM, ND, OD, DDS)	663	59
No qualifications listed	170	15
Pharmacist (RPh or PharmD)	139	12
Registered nurse (RN)	92	8
Nurse practitioner, Physician assistant	21	2
Medical technologist (MT)	13	1
Bachelor degree (BS or BA)	13	1
Other, includes: MS, MSW, PhD, MBA, EdD, JD, MPH, NHA	23	2

## Which waived tests are most popular?

The following shows the top ten waived tests according to the most common site types in Washington State.

Rank order	POL (N=1387 sites)	SNF (N=238 sites)	Clinic (N=189 sites)	Hospital (N=141 sites)	Pharmacy (N=136 sites)	IL (N=96 sites)
1	Urinalysis	Glucose	Urinalysis	Fecal occult blood	Glucose	Urinalysis
2	Fecal occult blood	Fecal occult blood	Fecal occult blood	Urinalysis	Cholesterol	No waived tests
3	Glucose	Urinalysis	Glucose	Glucose	Triglycerides	ESR
4	Pregnancy test	Gastric occult blood	Pregnancy test	Pregnancy test	Lipid profile	Fecal occult blood
5	Strep antigen	pH, body fluid	Strep antigen	ESR	HDL cholesterol	Strep antigen
6	Hematocrit	Ketones	Hematocrit	Strep antigen	H. pylori antibody	Pregnancy test
7	pH, body fluid	Prothrombin time	ESR	Hematocrit	Glycohemoglobin	Hematocrit
8	H. pylori antibody	Microalbumin	pH, body fluid	Gastric occult blood	Urinalysis	Prothrombin time
9	ESR	Cholesterol	Mononucleosis	No waived tests	Hemoglobin	Mononucleosis
10	Microalbumin	Creatinine, urine	H. pylori antibody	pH, body fluid	Fructosamine	Glucose
<b>POL</b> =Physician office laboratory; <b>SNF</b> =Skilled nursing facility; <b>IL</b> =Independent laboratory; <b>ESR</b> =Erythrocyte sedimentation rate						

A full report of this study (including a detailed listing of waived tests by all site types and by manufacturer and brand name) can be requested by calling (206) 361-2828. It can also be viewed and printed from the following CDC website address: [www.phppo.cdc.gov/dls/mlp/pnlmsmn.asp](http://www.phppo.cdc.gov/dls/mlp/pnlmsmn.asp). All other reports and references to published journal articles based on the studies of the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network project can also be accessed at this website address.

# Clinical Laboratory Initiative May 2002 Update

by Jon M. Counts, DrPH, MPH

**Teleconference:** A teleconference was held on April 16 to address quality assurance in clinical microbiology, including a special emphasis on antimicrobial susceptibility testing. Dr. Joe Campos, Children's Hospital in Washington, D.C. and Janet Hindler, UCLA, were our expert panel. One hundred and thirty seven sites in 7 states were registered for the teleconference. Over 420 participants heard the presentations.

**Train the Trainer workshop:** A number of individuals (21) from the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Laboratory Quality Assurance (LQA), local hospitals, laboratory training programs and microbiologists from other states in the region, were invited to participate in a Train the Trainer workshop in antimicrobial susceptibility testing (AST) on April 15th. Participants were trained by Janet Hindler in the use of the CDC interactive computer-based training program on AST as well as use of the CDC website (MASTER). They will serve as faculty for future technical workshops and as a resource to provide technical consultation on AST.

**Evaluation of quality improvement intervention strategies:** Questionnaire surveys will be sent to laboratories to evaluate whether or not intervention strategies implemented to date have resulted in any change in laboratory practice.

**Availability of January 2002 NCCLS Performance Standards for Antimicrobial Susceptibility Testing: 12<sup>th</sup> Informational Supplement (M100-S12):** Dr. David Tison, Multicare Health System (Tacoma), a member of the Initiative Steering Committee, has obtained several copies of this document **FREE OF CHARGE** to provide to laboratories through a generous donation by Roche Laboratories, Inc. Please contact me if you would like a copy for your use. (jcqueenanne@hotmail.com or 206-441-4441). Copies may also be obtained from the DOH Office of Laboratory Quality Assurance (206-361-2802).

**Initiative Website:** An internet site (<http://www.nwcp.org/cli/>) has been established for the Initiative and will be updated periodically. It covers the following:

- Description of Initiative
- Goals/objectives
- Current project on antimicrobial susceptibility testing
- Quality improvement intervention strategies
- Future activities

- Publications and documents
- Resources – links to other sites

**CDC Website:** Every laboratory manager, microbiologist, medical technologist/technician involved in antimicrobial susceptibility testing should become acquainted with and use the following CDC website: [www.phppo.cdc.gov/dls/master/default.asp](http://www.phppo.cdc.gov/dls/master/default.asp).

It is an excellent resource for information on AST including the following:

- Case studies
- Q & A
- Recent publications
- New information/upcoming CE
- Reference materials – links to other sites

**Assessment of Susceptibility Testing Practices for *Streptococcus pneumoniae* — United States, February 2000,** has been published in a recent issue of the CDC MMWR (May 10): [www.cdc.gov/mmwr/preview/mmwrhtml/mm5118a2.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5118a2.htm).

**ASM Website:** A website has been established by the American Society of Microbiology to address the competency assessment of laboratory personnel performing tests in clinical microbiology: [www.asmta.org/division/c/competency.htm](http://www.asmta.org/division/c/competency.htm).

**Focus Group Discussions:** A series of focus group discussions will be implemented during the year to solicit information on the following topics:

- Factors that a laboratory considers in the selection of methodology, technology and testing policies in clinical microbiology
- Verification and validation procedures utilized in the implementation of new methodology
- Factors that a laboratory considers in the adoption of national and local standards of laboratory practice
- Evaluation of microbiology services provided by referral laboratories (public and private)
- Factors that should be considered in the development of recommendations for clinical microbiology services that need to be provided by the laboratory delivery system

Lab managers, bench microbiologists/technologists, and clinicians will be invited to participate in focus group discussions that will be scheduled on a regional basis during this year and next.

# Personnel Shortage Workgroup Update

by Leonard Kargacin

The Clinical Laboratory Advisory Council Laboratory Personnel Shortage Workgroup held its latest meeting in Everett on April 25. Highlights of the meeting included:

**Program Updates:** Each program director provided information about the number of last year's graduates, their current enrollment, and their capacity. For the Clinical Laboratory Scientist (CLS) / Medical Technology (MT) programs there will be 33 graduates this year and 42 students starting in the programs this summer. For the Clinical Laboratory Technician (CLT) / Medical Laboratory Technician (MLT) programs there will be 34 graduates this year and 45 students starting in the programs this summer. The CLS/MT program at Sacred Heart Medical Center and the CLT/MLT program at Clover Park Technical College are operating at capacity. The other programs are not operating at full capacity.

## **Student recruitment activities:**

- The "Laboratory Science Profession" recruitment brochure is currently available at: [http://www.doh.wa.gov/hsqa/fsl/LQA\\_Home.htm](http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm) (select "Updates").
- Recruitment Website ([www.labcareers.org](http://www.labcareers.org)) is active.
- The "What career choices do I have with a science major?" brochure has been completed.
- **Medical Assistant Programs:** We continue to work with the medical assistant training programs to make their students aware of clinical laboratory career options.
- **Phlebotomy programs** are a good source of students. Several students in the CLT/MLT programs have been recruited into the profession while they were attending one of the phlebotomy training programs.
- **School counselors and science teachers:** A meeting for counselors and science teachers was held at the WSSCLS/NWSSAMT Spring Meeting in Everett on April 25.
- **Washington Science Teachers Association (WSTA):** The Workgroup presented an informational session at the WSTA meeting held in Yakima last fall.

**Recruitment Brochures Available:** The recruitment brochures mentioned above are available to anyone interested in helping promote laboratory careers. The files can be obtained by contacting Leonard Kargacin at (206) 361-2804 or [leonard.kargacin@doh.wa.gov](mailto:leonard.kargacin@doh.wa.gov).

**What can I do to help?** All personnel currently working in the clinical laboratory have a vested interest in recruiting more students into the field. You can:

- Encourage employers to provide a tuition reimbursement program for current employees who wish to further their education.
- Encourage employers to provide on-site training for students, remembering that they are potential employees;
- Be willing to give a little bit extra and assist in training students since the student might be a future employee and take some of the pressure off short-staffing;
- Be "upbeat" and positive when talking with people asking for information about the laboratory profession;
- Be aware of how our conversations in the lunchroom sound to new employees and students.

## CWU To Close Medical Technology Program - Yakima Area Hospitals To Pick Up Program

by Claudia Steen

Because of recent budget cuts to higher education by the State of Washington, officials at Central Washington University (CWU) decided to close their CLS/MT program as of July 2002. For the past 30 years this 3+1 program has been a model in cooperative effort, with funding coming not only from CWU, but also from both of the Yakima hospitals where students receive their clinical training. The CWU program has had 211 graduates, 63% of which have worked in central Washington for one or more years. About 33% of the graduates remain in the laboratory workforce today.

The Yakima area hospitals, in particular Yakima Valley Memorial Hospital and Yakima Providence Medical Center, have met and decided that, even in the face of today's financial concerns for hospitals, it is important to keep the CLS/MT program going. Details are still being worked out, but the new CLS/MT program will start the first class of students in July 2002! Thank you to the Yakima area hospitals for making the commitment to make this work.

# L&I to Initiate Rulemaking for Mandatory Cholinesterase Monitoring

by John Furman, PhD

The Department of Labor & Industries (L&I) has begun rulemaking to require red blood cell (RBC) and plasma cholinesterase monitoring of agricultural workers who handle certain pesticides, due to a February 2002 decision by the Washington State Supreme Court. In *Juan Rios and Juan Farias vs. Washington Department of Labor and Industries*, the court ordered L&I to initiate rulemaking for mandatory cholinesterase monitoring for agricultural workers who handle pesticides containing organophosphate and carbamate compounds. Organophosphate and carbamate pesticides inhibit the enzyme acetylcholinesterase, which is necessary for a balanced transmission of messages at the neural junction.

In 1997, pesticide handlers asked the Department to adopt a mandatory cholinesterase monitoring rule. The Department chose not to adopt a mandatory rule, but instead left in place the voluntary guideline in the existing rule, WAC 296-307-14520. The court determined that the Department's denial of the request for rulemaking was unreasonable because L&I had already determined a significant health risk and that there is a feasible method to reduce the risk.

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[http://www.doh.wa.gov/hsqa/fsl/LQA\\_Home.htm](http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm)

A cholinesterase monitoring program requires baseline testing prior to exposure followed by routine monitoring during the pesticide application season (e.g., every 30 – 60 days). Test results are interpreted as a percentage of the baseline. Ideally the same laboratory should perform all tests on a handler due to varying testing methods used by different laboratories. Current recommendations are that handlers be removed from exposure to organophosphate and carbamate pesticides if RBC cholinesterase levels drop below 70% of baseline, or plasma cholinesterase levels drop below 60% of baseline. Pesticide handling may resume when cholinesterase levels return to 80% or more of baseline.

Routine laboratory monitoring coupled with medical supervision of an employer's cholinesterase monitoring program can be used to identify unsafe work practices or conditions, trigger corrective interventions, and protect workers from toxic exposures.

The Department is working closely with stakeholders from labor advocacy groups, employer/grower representatives and other government agencies that may be impacted. This rulemaking activity is expected to take several months and public hearings will be held before a final rule is adopted. Interested parties can participate in the formulation of the proposed rule by contacting Cindy Ireland, Project Manager, Department of Labor and Industries WISHA Services Division, PO Box 44620, Olympia, WA 98504-4620, (360) 902-5522.

## Correction!

In the May 2002 issue of *Elaborations*, a symbol used in the article on Whole Blood Glucose Monitoring Devices was printed incorrectly. The sentence, found on the top of the second column on the first page, should read as follows: "A FPG (fasting plasma glucose) greater than or equal to 126 mg/dl is an indication for retesting, which should be repeated on a different day to confirm the diagnosis."

## Waived Testing Helpful Hints

A self-study PowerPoint presentation on Good Laboratory Practices can be found on the following website:

[http://www.doh.wa.gov/hsqa/fsl/LQA\\_Home.htm](http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm)

*Select the sidebar "Updates"*

*Select "Good Laboratory Practices with Waived Test Systems"*

**NOTE:** You do not need to have the Microsoft PowerPoint software loaded on your system to view this document.

### Calendar of Events

#### PHL Training Classes:

Waived Testing Exhibition

June 21 Shoreline

Blood Parasites

July 17-18 Shoreline

Shipping & Handling of Biohazardous Materials

August 27 Shoreline

August 28 Shoreline

#### Northwest Medical Laboratory Symposium

October 16 - 19 Portland

#### 9th Annual Clinical Laboratory Conference

November 11 Seattle

Contact information for the events listed above can be found on page 5. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 5. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.